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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,856	03/19/2004	Thomas C. Green	NEO-005 CON	7428
1473	7590	09/20/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP 1251 AVENUE OF THE AMERICAS FL C3 NEW YORK, NY 10020-1105			JEFFERY, JOHN A	
			ART UNIT	PAPER NUMBER
			3742	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/804,856	Applicant(s) GREEN ET AL.	
	Examiner John A. Jeffery	Art Unit 3742	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 22-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Trademark Usage in Application

The use of the trademark "TEFLON" has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-25, 27, and 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(1) Claims 23-25, 27, and 30 depend from cancelled claims 2-4, 6, and 9 respectively. For examination purposes, the examiner presumes applicant intended the following claim dependencies:

- claim 23 depends from claim 22
- claim 24 depends from claim 23
- claim 25 depends from claim 24
- claim 27 depends from claim 26

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- claim 30 depends from claim 29

(2) Claim 30 contains the trademark/trade name "TEFLON." Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. & Interf. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a polytetrafluorethylene constituent of a composite and, accordingly, the identification/description is indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grimm (US5938583) in view of Burr et al (US2001/0049510). Grimm (US5938583) discloses an apparatus for depositing radioactive seeds into a patient's prostate with an elongated needle adapted to receive a column of radioactive seeds and spacers. See abstract. According to col. 2, lines 24-26, the accurate and proper placement of the needle is "very important" to successful seed implantation. Moreover, improper insertion of the needle into the bladder is determined by visual techniques. Col. 4, lines 57-65.

The claim differs from Grimm in calling for providing conductive traces on the needle and circuitry associated therewith for determining whether the needle projects into the bladder. Burr et al (US2001/0049510) discloses the use of electrodes disposed on a needle for generating a signal indicating when the conducting portions have penetrated a body and reached a certain position. Note electrodes 122 and 123 disposed on insulative layer 121 in Fig. 10. See also Fig. 2 and Abstract. Note also resistor networks in Fig. 3. In view of Burr et al, it would have been obvious to one of ordinary skill in the art to provide an automatic detection means mounted on the needle in the apparatus of Grimm so that a detection system was used that was mounted on the needle itself thus precluding the need for additional sensing devices such as ultrasonic monitors and the like. Such an arrangement significantly reduces the number apparatus parts needed in the detection system.

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Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grimm (US 5,938,583) in view of Burr et al. (US 2001/0049510) and further in view of Lum et al. (US 6,391,005). The claim differs from the previously cited prior art in calling for the metallic films to consist of copper, nickel, or TEFLON/silver composite. But such materials for electrodes are well known in the art as evidenced, for example, by Lum et al. (US 6,391,005) noting the use of nickel as a conductive coating material on a needle to detect impedance changes. As is well known in the art, the claimed metals, such as nickel, are excellent electrical thin film conductors since they are easily applied by thin film techniques such as deposition. In view of Lum et al. (US 6,391,005), it would have been obvious to one of ordinary skill in the art at the time of the invention to use a metal such as nickel for the electrode material of the previously described apparatus to use a metal that was an excellent electrical conductor that is easily applied by thin film techniques such as deposition.

Claims 1, 28, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grimm (US 5,938,583) in view of DE4420232. Grimm (US5938583) discloses an apparatus for depositing radioactive seeds into a patient's prostate with an elongated needle adapted to receive a column of radioactive seeds and spacers. See abstract. According to col. 2, lines 24-26, the accurate and proper placement of the needle is "very important" to successful seed implantation. Moreover, improper insertion of the needle into the bladder is determined by visual techniques. Col. 4, lines 57-65.

The claim differs from Grimm in calling for providing conductive traces on the needle and circuitry associated therewith for determining whether the needle projects into the bladder. DE4420232 discloses a hollow needle or probe with means to detect the needle's penetration depth inserted into human tissue with first and second conductive traces (17, 18) that detect an "electromagnetic parameter value" such as resistance therebetween. See Abstract. In view of DE4420232, it would have been obvious to one of ordinary skill in the art to provide an automatic detection means mounted on the needle in the apparatus of Grimm so that a detection system was used that was mounted on the needle itself thus precluding the need for additional sensing devices such as ultrasonic monitors and the like. Such an arrangement significantly reduces the number apparatus parts needed in the detection system.

Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grimm (US 5,938,583) in view of DE4420232 and further in view of Burr et al. (US 2001/0049510). The claims differ from the previously cited prior art in calling for a layer of electrically insulating material on which the electrically conductive traces are disposed. But providing such a structure is well known in the art as evidenced, for example, by Burr et al. (US 2001/0049510) noting electrodes 122 and 123 disposed on insulative layer 121 in Fig. 10. Such a structure electrically isolates the electrodes from the needle, thus preventing shorting. In view of Burr et al. (US 2001/0049510), it would have been obvious to one of ordinary skill in the art at the time of the invention to provide an intervening insulative layer between the needle and the electrodes in the

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previously described apparatus to electrically isolate the electrodes from the needle, thus preventing shorting.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grimm (US 5,938,583) in view of DE4420232 and further in view of Lum et al. (US 6,391,005). The claim differs from the previously cited prior art in calling for the metallic films to consist of copper, nickel, or TEFLON/silver composite. But such materials for electrodes are well known in the art as evidenced, for example, by Lum et al. (US 6,391,005) noting the use of nickel as a conductive coating material on a needle to detect impedance changes. As is well known in the art, the claimed metals, such as nickel, are excellent electrical thin film conductors since they are easily applied by thin film techniques such as deposition. In view of Lum et al. (US 6,391,005), it would have been obvious to one of ordinary skill in the art at the time of the invention to use a metal such as nickel for the electrode material of the previously described apparatus to use a metal that was an excellent electrical conductor that is easily applied by thin film techniques such as deposition.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grimm (US 5,938,583) in view of Burr et al. (US 2001/0049510) or DE4420232 and further in view of Whaley et al (US2763935). The claims differ from the previously cited prior art in calling for a reusable handle and the circuitry to be disposed within the handle. Providing a handle in conjunction with a needle and corresponding impedance

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measuring system is conventional and well known in the art as evidenced by Whaley et al (US2763935) noting Figs. 18-21 and col. 11, lines 5 - 53. Note meter 83 in Fig. 18.

Providing the circuitry in the handle precludes the need to provide an additional housing for the measurement circuitry and reduces the number of apparatus parts. In view of Whaley et al (US2763935), it would have been obvious to one of ordinary skill in the art to provide the impedance measurement circuitry in a reusable handle in the previously described apparatus in order to preclude the need to provide an additional housing for the measurement circuitry and reduces the number of apparatus parts.

Regarding claim 25, the use of a light meter in lieu of an analog or digital impedance meter is not seen to be critical and would have been obvious to one of ordinary skill in the art in view of a light meter's ability to display relative intensities at a distance from the meter.

Response to Arguments

Applicant's arguments filed 7/19/05 have been considered but are not deemed to be persuasive. Applicant argues that the combination of Grimm with Burr and DE4420232 is improper because Grimm allegedly teaches away from the secondary references. To support this assertion, applicant notes that because Grimm teaches that the operator will recognize needle insertion into the bladder will be apparent upon noticing urine in the needle or ultrasonic probes, there is allegedly no need for any other detection system. Remarks, at 7.

The examiner, however, respectfully disagrees. Merely because Grimm does not use an automatic needle-based impedance detection system does not foreclose its use. On the contrary, an automatic detection means mounted on the needle in the apparatus of Grimm would, in fact, be highly desirable to the skilled artisan. As noted in the rejections, such a detection system suggested by the secondary reference would be beneficial in the system of Grimm (US 5,938,583) in that the detector would be mounted on the needle itself thus precluding the need for additional sensing devices such as ultrasonic monitors and the like. Moreover, such an automatic detection system would preclude the need to constantly visually monitor the needle for urine, thus freeing the operators for other surgical tasks. The references are properly combinable and the rejection is proper.

Final Rejection

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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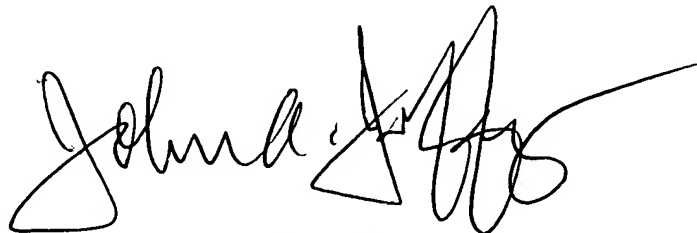
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John A. Jeffery whose telephone number is (571) 272-4781. The examiner can normally be reached on Monday - Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans, can be reached on (571) 272-4777. All faxes should be sent to the centralized fax number at (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read 'John A. Jeffery', with a long, sweeping horizontal line extending to the right.

**JOHN A. JEFFERY
PRIMARY EXAMINER**